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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------------|---------------------|------------------|
| 10/583,658 | 03/12/2007 | Rachid Zegdi | 2006_0999A | 3730 |
| 513 7590 01/31/2012 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503 | | | | |
| EXAMINER MILLER, CHERYL L | | | | |
| ART UNIT 3738 | | PAPER NUMBER | | |
| NOTIFICATION DATE 01/31/2012 | | DELIVERY MODE ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com
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Office Action Summary**Application No.**

10/583,658

Applicant(s)

ZEGDI, RACHID

Examiner

CHERYL MILLER

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-4,6-9,11-13 and 15-18 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 1-4,6-9,11-13,16-17 is/are allowed.
- 7) ☒ Claim(s) 15 and 18 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CIBIS)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date ____

IDETAILED ACTION

Response to Arguments

Applicant's arguments filed January 9, 2012 have been fully considered but they are not persuasive. The applicant has argued that Garrison's winding 31 may not be considered the constriction strand since it is part of the support structure 26. To further clarify the examiners position (since it may have not been clear enough since there are two windings 31;28 and 30) the carrier frame may be considered entire stent 26 or just the upper portion of stent 26 (upper winding 28). When the resilient carrier is considered upper winding alone (28), the constriction strand may be considered lower winding (30), it extends around the periphery/circumference of 28 along valve base 41, thus under this interpretation, it is the examiners position that Garrison discloses all features of the claim.

However, in the case that lower winding (lower 31; i.e. 30) of Garrison may not be considered a constriction strand, Bolea teaches use of constriction strands on stents. The examiner had pointed to two separate embodiments of Bolea in the previous action, that of figures 8-10 and that of figures 19-21, both applicable and combinable with Garrison.

The applicant has argued that Bolea's strand 80 of figures 8-10, as it protrudes slightly into the lumen, would interfere with the function of Garrison's valve. The examiner disagrees. Strand 80 may be placed at the proximal end, distal end or any place along the stent (Bolea P0064; P0046), thus may be placed at bottom end 35 of Garrison's stent (when Garrison's resilient carrier frame is all of 26, Bolea's strand 80 may be placed around or threaded through winding 30 of stent 26; thus even if a small portion of the strand protrudes into the lumen, it

would not contact or interfere with the opening and closing of the valve, since the strand would be placed a distance from the valve).

Further, the other embodiment cited, seen in figures 19-21 of Bolea places a constriction strand through eyelet on a stent so that no portion of the strand protrudes into the lumen. Since Garrison coil 36 is comprised of a plurality of eyelets, Bolea's teaching of a constriction strand 80 through eyelets (figs.19-21), may be applied to the eyelets of Garrison, such that Bolea's strand 80 extends through the eyelets in 36 (and thus not protruding into the lumen and not interfering with the function of the valve).

The applicant has also argued that insertion of Bolea's removal tool on Garrison's stent would damage Garrison's valve 38. It is the examiners position that a specific type of removal tool is not claimed, thus the tool shown by Bolea is not necessarily required. Further, Bolea discloses alternate removal tools other than that shown may be used and the tool may pull the strand *axially* instead of twisting (P0060, P0065, P0071). Also, whether or not Garrison's valve 38 is damaged by a removal tool is irrelevant, because the strand is constricted when the stent (and thus valve) are being removed from the body because they are defective, this is the purpose of the constriction strand-for removal. Thus if the valve is damaged by a removal tool as it is being removed does not matter, as it will be discarded anyway when pulled out of the body.

Constriction strands on stents and stent valves are well known in the art, see additional prior art cited in the most previous office action (Soetikno US 2002/0143387, Berg US 7,252,681 for example).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. (US 6,425,916 B1, cited previously) in view of Bolea et al. (US 2002/0188344 A1, cited previously). Garrison discloses a kit for placement in a duct substantially as claimed. Garrison discloses a kit (fig.9) comprising a tubular endoprosthesis (8; fig.8) and a prosthetic valve (6; fig.10), the valve configured to be implanted in and removed from the tubular endoprosthesis (is unattached separate component, thus has *capability* of being removed therefrom; shown in figures to be inserted into body separately as well), the valve (6; fig.10) having a resilient carrier frame (entire 26 or an upper portion of 26; col.8, lines 14-21; col.9, lines 1-10), and flexible shutter (leaflets 38). Garrison discloses the shutter (leaflets 38) to have an obstructed position (closed) in which it is extended transverse to the lumen (see fig.11) and a released position when the shutter is contracted transversely to the central axis (leaflets open to be parallel with lumen thus are contracted along the transverse plane-relative to the transverse plane, at the rim/perimeter of the valve). Garrison shows a centripetal compression means comprising a constriction strand for compressing the carrier frame (lower winding 31; i.e. 30 shown as a closed loop and is *capable of being grasped* by instrumentation and pulled inward to compress the stent). In the case that lower winding 31 (30) may not be considered the constriction strand, Bolea teaches in the same field of resilient frames (stents), the use of a constriction strand (80; figs.8-10 or 19-21) in the form of a closed loop attached to an end of a

resilient frame (10; P0001, P0039-P0040, similar to Garrisons frame 26), in order to provide a means for removing or repositioning the frame if needed (P0009, P0049, P0050, P0060). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Bolea's teaching of placing closed loop constriction strands on stents/resilient frame (either around an end of stent, woven in and out of stent as seen in figs.8-10 or through eyelets in a stent as seen in figs.19-21), with the resilient frame of Garrisons system (seen in fig.9; Bolea's strand 80 may be provided around Garrison's stent end 35; woven through Garrison's lower winding 30; or threaded through Garrison's eyelets 36), in order to provide a mean for removing the inner stent valve (26) from the body.

Allowable Subject Matter

Claims 1-4, 6-9, 11-13 and 16-17 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Cheryl Miller whose telephone number is 571-272-4755. The examiner can normally be reached on M- F (8am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Thomas Sweet at 571-272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738
/THOMAS J SWEET/
Supervisory Patent Examiner, Art Unit 3738